DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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August 22, 2014

FujiFilm Medical Systems U.S.A., Inc.
Mary K. Moore
Senior Director, Regulatory Affairs and Quality
10 High Point Drive
Wayne, NJ 07470

Re: K140149
Trade/Device Name: EPX-4440HD Digital Video Processor with FICE and Light Source
Regulation Number: 21 CFR§ 876.1500
Regulation Name: Endoscopes and accessories
Regulatory Class: II
Product Code: PEA, FET, GCT
Dated: July 18, 2014
Received: July 18, 2014

Dear Mary K. Moore,

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies.

You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Herbert P. Lerner -S

for

Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: December 31, 2013
See PRA Statement on last page.

510(k) Number *(if known)*

K140149

Device Name
EPX-4440HD Digital Video Processor with FICE and Light Source

Indications for Use *(Describe)*

Indications for Use (VP-4440HD with FICE):

The VP-4440HD unit is used for endoscopic observation, diagnosis, treatment, and image recording. It is intended to process electronic signals transmitted from a video endoscope (a video camera in an endoscope). This product may be used on all patients requiring endoscopic examination and when using a Fujinon/Fujifilm medical endoscope, light source, monitor, recorder and various peripheral devices. FICE is an adjunctive tool for gastrointestinal endoscopic examination which can be used to supplement FUJIFILM white light endoscopy. FICE is not intended to replace histopathological sampling as a means of diagnosis.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) □ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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K140149

510(k) SUMMARY

FUJIFILM Medical Systems U.S.A., Inc.'s
EPX-4440HD Digital Video Processor with FICE and Light Source

Date: August 20, 2014

Submitter's Information:
FUJIFILM Medical Systems U.S.A., Inc., Endoscopy Division
10 High Point Drive
Wayne, NJ 07470 USA
FDA Establishment Registration Number: 2431293

Contact Persons:
Mary K. Moore
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E-Mail: mkmoore@fujifilm.com

Identification of the Proposed Device:

Proprietary/Trade Name: Fujifilm EPX-4440HD Video Processor with FICE and Light Source
Common Name: Endoscopic Video Processor and Light Source
Classification Information:

Classification Name	CFR Section	Product Codes
Endoscope, accessories, image post-processing for color enhancement	21 CFR 876.1500	PEA
Endoscopic Video Imaging System/Component, Gastroenterology-Urology.	21 CFR 876.1500	FET
Light source, Endoscope, Xenon Arc	21 CFR 876.1500	GCT

Predicate Devices:

- Fujifilm Medical Systems U.S.A., Inc.'s EPX-4440HD Digital Video Processor and Light Source (K102466)
- Olympus Medical Systems Corp.'s EVIS EXERA II 180 System (K100584)

Indications for Use

Indications for Use (VP-4440HD with FICE):

> The VP-4440HD unit is used for endoscopic observation, diagnosis, treatment, and image recording. It is intended to process electronic signals transmitted from a video endoscope (a video camera in an endoscope). This product may be used on all patients requiring endoscopic examination and when using a Fujinon/Fujifilm medical endoscope, light source, monitor, recorder and various peripheral devices. FICE is an adjunctive tool for gastrointestinal endoscopic examination which can be used to supplement FUJIFILM white light endoscopy. FICE is not intended to replace histopathological sampling as a means of diagnosis.

Device Description

This system is intended to be used in conjunction with Fujinon/Fujifilm endoscopes to provide illumination, visual display and data storage during endoscopic procedures.

The EPX-4440HD Digital Video Processor with FICE and light source consists of three components used in conjunction with one another:

> The VP-4440HD Video Processor: The Processor relays the image from the endoscope to a video monitor. Projection can be either analog or digital at the user's preference. The Processor incorporates internal or external digital storage capacity. The Processor also controls the light projected to the body cavity. The Processor provides for optional structural enhancement at the user's option. Spectral and structural enhancements are achieved through proprietary software. The device is AC operated at a power setting of 120V/60MzJ0.8A. The Processor is housed in a steel-polycarbonate case measuring 390x105x460mm.
>
> The XL-4450 Light Source: The Fujinon/Fujifilm endoscope employs fiber bundles to transmit light from the light source and subsequently to the body cavity. The Light Source employs a 300W Xenon lamp with a 75W emergency back-up Halogen lamp. Brightness control is performed by the user. The device is AC operated at a power setting of 120V/60MzJ3.3A. The Light Source is housed in a steel-polycarbonate case measuring 390x155x450mm.
>
> The DK-4440E Keyboard: The Keyboard is used to enter pertinent procedural information (patient, physician, date, etc.) for display on the video monitor and digital/analog storage systems. The Keyboard is also used to control operational features of the VP-4440HD Processor. The Keyboard resembles a standard computer keyboard in size and shape.

The VP-4440HD Digital Video Processor with FICE and light source is the same as the cleared EPX-4440HD Digital Video Processor and Light source (K102466) device, with the exception of the addition of the imaging algorithm termed “FICE” (Flexible spectral-Imaging Color Enhancement). As with the predicate device, the subject processor receives an image from the endoscope via a connector cable. The subject processor is capable of bi-directional communication that allows

importation and exportation of various patient and procedural data between EMR (Electronic Medical Record) systems.

FICE is an image processing feature that a licensed medical practitioner (user) can utilize, as an adjunctive tool, to supplement the white light endoscopic examination. FICE extracts spectral images of specific wavelength components from the original full spectral (white light) image through an image processing algorithm that, assigns a spectral wavelength component in the Red (R), Green (G) and Blue (B) spectrum and displays the enhanced color image. FICE may enhance color contrast to improve visibility of the selected structures, borders of areas of interests.

Performance Testing

Non-clinical testing:

The EPX-4440HD Digital Video Processor is non-sterile and has no potential for patient contact. Testing of the VP-4440HD with FICE consisted of software validation in accordance with IEC 62304 and electrical safety in accordance with IEC 60601 requirements. Functional testing of the FICE image processing feature included contrast enhancement, dynamic range, resolution, noise, artifact creation, and color reproduction. All testing criteria were met, and in all instances the device functioned as intended.

Clinical testing:

The FICE feature was evaluated in a prospective clinical trial to objectively assess the overall image quality of each of the FICE presets in comparison to optical filtering of the white light source. The study design was a reader concurrence study designed in accordance with the FDA document "Guidance on Solid State X-ray Imaging Devices, and consisted of two parts: (1) acquisition of images; and (2) reader study. Each subject underwent two (2) gastrointestinal endoscopic examinations during a single clinical procedure, one with the Olympus EVIS EXERA II 180 System (White Light Imaging (WLI) and Narrow Band Imaging (NBI)), and one with the subject Fujifilm EPX-4440HD Digital Video Processor and compatible videoendoscope (WLI and all 10 FICE modes). Images were taken from different anatomic locations within the gastrointestinal tract (i.e., colon, duodenum, esophagus, or gastric region), and analyzed independently by multiple blinded investigators using a 4-point Likert scale. The goal of the clinical study was to establish that FICE demonstrated substantial equivalence of diagnostic visualization (e.g. image quality) to the predicate optical filtering method through a direct comparison between the two imaging modalities. Overall means between all readers demonstrated at least comparable image quality of each FICE setting in one or more locations within the gastrointestinal tract."

Substantial Equivalence

The EXP-4440HD Digital Video Processor with FICE and Light Source is substantially equivalent to the EXP-4440HD Digital Video Processor and Light Source and the Olympus EVIS EXERA II 180 System. The EXP-4440HD Digital Video Processor with FICE and Light Source has the same intended use and similar indications, technological characteristics, and principles of operation as its predicate devices. The minor technological differences between the EXP-4440HD Digital Video Processor with FICE and Light Source and its predicate devices raise no new issues of safety or effectiveness. Performance data demonstrate that the EXP-4440HD Digital Video Processor with FICE and Light Source is as safe and effective as the EXP-4440HD Digital Video Processor and

Light Source and the Olympus EVIS EXERA II 180 System. Thus, the EXP-4440HD Digital Video Processor with FICE and Light Source is substantially equivalent.

Conclusions:

The Fujifilm EPX-4440HD Digital Video Processor with FICE and Light Source is substantially equivalent to similar legally marketed devices and conforms to applicable medical device safety and performance standards.